

REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and present specification.

Status of the Claims

In the present Reply, claims 3, 8 and 9 have been amended, and claims 10 and 11 have been added. Also, claim 2 was previously canceled without prejudice or disclaimer of the subject matter contained therein. Thus, claims 1 and 3-11 are pending in the present application. No new matter has been added by way of these amendments and new claims because each amendment and new claim is supported by the present specification.

For example, the amendments to claims 3, 8 and 9 correct grammatical errors and/or are minor in character. Applicants note that these are clarifying and not narrowing amendments. By deleting/amending these terms in order to clarify the claimed invention (e.g., "composition" to "food" in claim 9), Applicants in no way are conceding any limitations with respect to the interpretation of the claims under the Doctrine of Equivalents.

New claims 10 and 11 drawn to other embodiments of the present invention have been added for the Examiner's consideration. Support for new claims can be found in originally filed claim 1 as well as pages 5-6 of the present specification.

Also, no new matter has been added with the amendments to the present specification since one of skill in the art would understand that these corrections are merely editorial in nature.

Based upon the above considerations, entry of the present amendments is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 103(a)

Claims 1 and 3-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 01/07135 (Pisacane et al.; hereinafter referred to as “WO ‘135”) or U.S. Patent 6,063,382 (Nakajima et al.; “Nakajima ‘382”), both in view of Sakai et al. (*Agric. Biol. Chem.*, Vol. 54(4), pp. 879-889 (1990); “Sakai”) and EP 0 880 894 A1 (Sato et al.; “EP ‘894”), and further in view of newly cited Sato et al. (U.S. Patent No. 5,958,419; “Sato ‘419”) (see pages 3-7 of the Office Action). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested. Overall, Applicants do not concede that *prima facie* cases of obviousness have been established.

All Rejections citing WO ‘135 as the Primary Reference

Applicants note that the cited WO ‘135 reference is not considered prior to the priority date of the present application. Specifically, WO ‘135 has a publication date of February 1, 2001, which is after the earliest priority date of the present application (June 23, 2000). Thus, any rejection citing the WO ‘135 reference has been overcome and/or rendered moot.

Distinctions over Remaining Rejections Citing Nakajima '382 as the Primary Reference

Applicants respectfully submit that a *prima facie* case of obviousness has not been established in that the Sato '419 is improperly cited and combined with the other references of Nakajima '382 (the primary reference), Sakai and EP '894.

The cited secondary reference of Sato '419 reference discloses using an extract in food to relieve the action of histamine (see Abstract; see also column 1, lines 5+). Further, the Examiner refers Applicants to column 2, lines 60-65 of Sato '419, as shown in the paragraph bridging pages 3-4 of the Office Action. This part of Sato '419 states:

. . . When the extracted stock solution is stored in a container at ordinary temperature, spores of yeast existing in the plant tissue of Stevia germinate and ferment to fill the container with carbon dioxide.

This description in Sato '419 thus discloses that (i) there are spores of yeast existing in the plant tissue of Stevia; and that (ii) these spores germinate in the extract of Stevia at an ordinary temperature. Since spores of yeast germinate in the extract of Stevia, Applicants submit that there is nothing to inhibit the germination of spores in the extract of Stevia as described in Sato '419 (in comparison to the Examiner's comments in the Office Action at page 5, lines 7-8; page 4, lines 12-18). Also, the production of carbon dioxide (see column 2, lines 61-62) does not affect spore germination. Thus, the Examiner's comments regarding the disclosure of Sato '419 is in contrast to what is instantly claimed. Specifically, the antibacterial substance obtained by the process of the present invention can inhibit germination of spores from spore-forming bacteria and koji mold. This is not true in Sato '419 as discussed above. Thus, Sato '419 does

not account for the deficiencies of the other cited reference and has been improperly combined with these other cited references.

Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established since U.S. case law squarely holds that a proper obviousness inquiry requires consideration of three factors: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; (2) whether or not the prior art would have taught, motivated, or suggested to those of ordinary skill in the art that they should make the claimed invention (or practice the invention in case of a claimed method or process); and (3) whether the prior art establishes that in making the claimed invention (or practicing the invention in case of a claimed method or process), there would have been a reasonable expectation of success. *See In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *see also In re Kotzab*, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000); *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). Here, not even the initial requirement of disclosure of all claimed features has been satisfied. Thus, this § 103(a) rejection is improper, and Applicants request withdrawal of the rejection.

Further Applicants respectfully submit that Sato '419 is improperly cited, since this secondary reference is directed to an antihistamine substance, and is not directed to an antibacterial substance. Therefore, Applicants respectfully submit that Sato '419 is in a non-analogous art with any of the other cited references or even with the present invention, making the citation of Sato '419 as improper. As stated by the Federal Circuit in *In re Oetiker*:

We have reminded ourselves and the PTO that it is necessary to consider "the reality of the circumstances", *In re Wood*, 599 F.2d 1032, 1036, 202 USPQ 171, 174 (CCPA 1979) -- in other words, common sense -- in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to

the problem facing the inventor. It has not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments. The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge can not come from the applicant's invention itself.

24 USPQ2d 1443, 1446 (Fed. Cir. 1992) (citing *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); *In re Geiger*, 815 F.2d 686, 687, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1147, 227 USPQ 543, 551 (Fed. Cir. 1985).

Here, Applicants submit that the Examiner has not provided adequate reasons to rely on this nonanalogous art (Sato '419), wherein the Examiner merely relied on a conclusion as to how a person faced with the particular problem at hand (e.g., spore germination) would look to the nonanalogous art because the nonanalogous art would solve the problem that the present invention solved (see the Office Action at page 4). Also, Applicants respectfully submit that it has not been established in the Office Action as to how one of ordinary skill in this art would reasonably expect to be successful or be motivated in referring to a reference directed to antihistamine substances in order to solve the problems associated with the art of the present invention. Thus, Applicants respectfully submit that Sato '419 is in a non-analogous art and has been improperly cited and combined with the other references of Nakajima '382, Sakai and EP '894. Reconsideration and withdrawal of all rejections citing Sato '419 are respectfully requested.

In addition, Applicants respectfully disagree as to how the cited references could be combined as done in the Office Action. Specifically, in response to Applicants' previous argument that the instantly claimed method inhibits germination of spores from spore-forming bacteria but not vegetative cells, the Examiner's responds as shown at page 5, lines 7-12 of the Office Action. Other related comments by the Examiner are shown at page 4, lines 19+ of the Office Action. Regarding these comments, Applicants respectfully traverse and question how the Examiner arrived at these conclusions in the Office Action.

In particular, the Examiner has not provided any scientific evidence to support such conclusions in the Office Action. If the Examiner continues to maintain that selecting certain protopectinase is "clearly within the skill of an ordinary artisan", and that the claimed temperature and pH ranges are a matter of optimization, Applicants hereby challenge these assertions. Applicants request that the Examiner produce evidence to support this assertion with explicit findings on motivation and reasonable expectation of success to select the claimed invention. *See In re Dillon*, 919 F.2d 688, 693, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (*en banc*), *cert. denied*, 500 U.S. 904 (1991); *In re Mills*, 680 F.2d 680, 683, 16 USPQ2d 1430, 1433 (Fed. Cir. 1990); *see also* M.P.E.P. § 2144.08(III).

Alternatively, if the Examiner is relying upon personal knowledge to support the finding of what is known in the art, the Examiner is respectfully requested to provide an affidavit or declaration setting forth specific factual statements and explanations to support such an assertion. In this regard, the Examiner is referred to 37 C.F.R. § 1.104(d)(2) and *In re Sang Su Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002) (the Federal Circuit held that the Board of Appeals could not

merely rely on what is “common-knowledge and common sense” in the art to sustain a rejection under 35 U.S.C. § 103). There was no proper motivation found in the *Lee* case since the U.S.P.T.O. failed to identify the specific principle known to one of ordinary skill in the art that suggested the claimed method. With regard to motivation or suggestion to select the instantly claimed invention, Applicants note that any conclusory statements of similarity or motivation, without any articulated rationale or evidentiary support, do not constitute sufficient factual findings. *See* M.P.E.P. § 2144.08(III).

Applicants also respectfully traverse the Examiner’s comments in the Office Action shown at page 6, lines 1-3. Specifically, the Examiner’s reasoning is such that any reference that discloses extraction or disintegration of plant tissue can be used until the present invention is eventually received. Thus, Applicants respectfully submit that the Examiner’s “motivation” is essentially an improper “obvious to try” rationale since a certain amount of experimentation would be involved until one of skill in the art eventually achieves what is instantly claimed. Applicants note that: “Obviousness requires one of ordinary skill in the art have a reasonable expectation of success as to the invention — ‘obvious to try’ and ‘absolute predictability’ are incorrect standards.” *Velander v. Garner*, 68, USPQ2d 1769, 1784 (Fed. Cir. 2003) (citing *In re O’Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673 (Fed. Cir. 1988)). Thus, the requisite reasonable expectation of success is lacking and this rejection is improper and/or has been overcome. *In re Vaack*.

Also, Applicants respectfully disagree with the application of EP ‘894 to form the instant rejection, and respectfully maintain that EP ‘894 is improperly interpreted. In particular, the

Examiner at page 4, lines 11-12 of the Office Action asserts that EP '894 teaches the bacteriocide composition that inhibits germination of spores from spore-forming bacteria and koji mold from a plant that provides for spores. However, Applicants respectfully disagree since EP '894 merely shows that the Stevia extract was unable to kill *Bacillus cereus* completely, and that some *B. cereus* survived in spore form. EP '894 also fails to disclose an antibacterial substance which inhibits the germination of spores from spore-forming bacteria or koji mold. Thus, since EP '894 does not teach the bacteriocide composition which inhibits germination of spores from spore-forming bacteria and koji mold from a plant that provides for spores as asserted, and Applicants submit that this reference has been improperly cited and combined with the other references. Withdrawal of this rejection is respectfully requested.

Further, Applicants disagree with the use and interpretation of Sakai et al. (*Agric. Biol. Chem.*). In particular, at page 5, lines 13-16 of the Office Action, the Examiner refers to Sakai as teaching "that protopectinase has potent activity upon plant tissue and to replace solvent extraction with enzyme extraction or degradation for providing an antibacterial substance is well within the teachings of the cited prior art". However, Applicants respectfully submit this fact in Sakai cannot be located. Instead, the cited Sakai reference is directed to a new protopectinase that has potent activity on sugar beet pulp, but less activity on lemon peel protopectin (see Abstract; page 889, lines 5-8). Also, Sakai states that there is the enzyme which may split the polysaccharide domain that connected the pectin molecule to the cell wall substances (page 888, right column, lines 13-15). Applicants cannot locate the disclosure in Sakai that supports the Examiner's position. Thus, if the Examiner maintains Sakai discloses such, Applicants request

that those parts of Sakai be described. In the alternative, if the Examiner is relying upon personal knowledge to support the finding of what is known in the art, the Examiner is respectfully requested to provide an affidavit or declaration setting forth specific factual statements and explanations to support such an assertion.

Overall, Applicants respectfully submit that all rejections have been overcome. First, WO '135 is not prior to the present application. Second, with regard to the remaining rejection citing Nakajima '382 as the primary reference, a *prima facie* case of obviousness has not been established, and that this rejection has been overcome for the reasons stated above. Accordingly, reconsideration and withdrawal of these rejections are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

Application No. 10/069,182

Docket No.: 0397-0441P

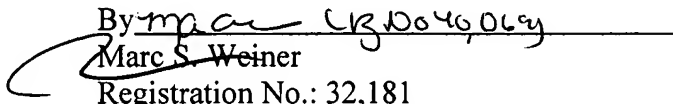
Art Unit 1651

Reply to Office Action of June 29, 2005

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: September 29, 2005

Respectfully submitted,

By  _____

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